Section 10: REVISED 510(K) SUMMARY

FEB 14 2014

Sponsor Information:

Name of 510(k) sponsor:	GlycoBioSciences, Inc.
Address:	7 Timber Court Georgetown, Ontario L7G 4S4 Canada
Contact information:	Kevin Drizen President GlycoBioSciences, Inc. 7 Timber Court Georgetown, Ontario L7G 4S4 - Canada Phone: 905-854-0631 Fax: 905-702-1709 kdrizen@glycobiosciences.com

Device Information:

Proprietary names of device: L.A.M. IPM Wound Gel and IPM Derm Gel

Generic/classification name: Dressing, Wound, Drug

Product code (classification): FRO

Legally Marketed Predicate Devices:

- Carrasyn Hydrogel Wound Dressing (K962218); September 12, 1996
- Epicyn HydroGel (K102945); February 2, 2011
- MimyX Cream (K041342); July 19, 2005
- L.A.M. IPM Wound Gel (K020325); April 15, 2002
- L.A.M. IPM Wound Gel (K123113); December 11, 2012

Device Description:

L.A.M. IPM Wound Gel/IPM Derm Gel is a clear viscous, odourless, aqueous gel, composed principally of sodium hyaluronate, a derivative salt of Hyaluronic acid. The proportion of sodium hyaluronate "w/w" in the formulation is 2.5%.

Hyaluronic acid is a molecule which is normally found in various parts of the body. Hyaluronic acid in L.A.M. IPM Wound Gel and IPM Derm Gel is derived from avian sources. L.A.M. IPM Wound Gel and IPM Derm Gel serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process. L.A.M. IPM Wound Gel/ IPM Derm Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Other ingredients in L.A.M. IPM Wound Gel and IPM Derm Gel are as follows:
hydroxyethyl cellulose (1%), methylparaben (0.2%), as well as polyethylene glycol (3%) and purified water, USP (approx. 93%).

L.A.M. IPM Wound Gel and IPM Derm Gel are presented in carton boxes with 4 laminated tubes of 10g (0.35oz).

L.A.M. IPM Wound Gel and IPM Derm Gel are exactly the same in every aspect and specifications; they are the same device with two (2) different trade names.

Intended Use:

L.A.M. IPM Wound Gel and IPM Derm Gel serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.
L.A.M. IPM Wound Gel/ IPM Derm Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Indications for Use:

"OTC":

L.A.M. IPM Wound Gel/IPM Derm Gel is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.

Rx:
Under the supervision of a health care professional;

• L.A.M. IPM Wound Gel/IPM Derm Gel is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and for second degree burns.

• L.A.M. IPM Wound Gel/IPM Derm Gel is indicated for the management and relief of burning, itching and pain associated with various types of dermatoses; including atopic dermatitis, allergic contact dermatitis and radio-dermatitis.

Device Technological Characteristics:

L.A.M. IPM Wound Gel/IPM Derm Gel is a clear viscous, odorless, aqueous gel. Hyaluronic acid is a molecule which is normally found in various parts of the body. Hyaluronic acid in L.A.M. IPM Wound Gel and IPM Derm Gel is derived from avian sources.
L.A.M. IPM Wound Gel and IPM Derm Gel serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.
L.A.M. IPM Wound Gel/ IPM Derm Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Products for topical use have their safety established through biocompatibility tests. The biocompatibility test performed for L.A.M. IPM Wound Gel, included reports of Cytotoxicity Study, Modifiied ISO Accute Reactivity in Rabbits, ISO Accute Systemic Toxicity in Mouse, In Vitro Hemolysis and ISO Sensitization. All of them meet the requirements of the ISO 10993 and resulted under the anticipated specifications.

Concluding, the biocompatibility test for L.A.M. IPM Wound Gel demonstrated similar results to the ones of its predicates, which is: the product safe and effective for its intended use.

Also, stability testing conducted to support the proposed shelf life confirmed that aged product met the acceptance criteria.

Comparison with Predicate Device:

L.A.M. IPM Wound Gel (K123113) is similar in technological characteristics and indications to the predicates.

510(k) Number	Proprietary Name	Product Code	Classification Name	Manufacturer	Classification Panel
K962218	Carrasyn Hydrogel Wound Dressing	MGQ	Dressing, Wound and Burn, Hydrogel W/Drug and/or Biologic	Carrington Laboratories Inc.	General & Plastic Surgery
K102945	Epicyn HydroGel	FRO	Dressing, Wound, Drug	Oculus Innovative Sciences Inc.	General & Plastic Surgery
K041342	MimyX Cream	MGQ	Dressing, Wound and Burn, Hydrogel W/Drug and/or Biologic	Stiefel Laboratories Inc.	General & Plastic Surgery
K020325	L.A.M. IPM Wound Gel	MGQ	Dressing, Wound and Burn, Hydrogel W/Drug and/or Biologic	LAM Pharmaceutical Corp.	General & Plastic Surgery
K123113	L.A.M. IPM Wound Gel	MGQ	Dressing, Wound and Burn, Hydrogel W/Drug and/or Biologic	GlycoBioSciences, Inc.	General & Plastic Surgery

Considering that the change of indication proposed by this 510(k) only includes indications that are already approved to the predicates indicated by Glyco, it is fair to understand that quality, safety and effectiveness are demonstrated and are comparable to the predicates.

Analysis of why any differences between the subject device and predicate(s) do not render the device NSE

Though L.A.M. IPM Wound Gel/ IPM Derm Gel contain different materials compared to some of the predicates, the basic technological characteristics of L.A.M. IPM Wound Gel/ IPM Derm Gel and all the predicates listed are the same; all devices provide a moist environment and protective barrier that retains moisture; this is beneficial in the wound healing process and also in the relief of symptoms associated with dermatitis. Similar to other cases of dermatitis treatment with emollients and dressings with wet wrap is recommended for the management of atopic eczema. This is the principle of operation of L.A.M. IPM Wound Gel/ IPM Derm Gel and all its predicates; provide and retain moisture on skin and wounds environments.

We used as a source of our understanding the publication "Management of atopic eczema in primary care. A national clinical guideline. 2011 Mar. NGC:008790"

In summary, L.A.M IPM Wound Gel/IPM Derm Gel is similar in function and intended use as its predicates; Epicyn HydroGel (K102945), Carrasyn Hydrogel Wound Dressing (K962218), MimyX Cream (K041342), L.A.M IPM Wound Gel (K020325) and L.A.M IPM Wound Gel (K123113)listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 14, 2014

GlycoBioSciences, Inc.
Kevin Drizen
President
7 Timber Court
Georgetown, Ontario, L7G 4S4, Canada

Re: K130781
Trade/Device Name: L.A.M. IPM™ Wound Gel and IPM Derm Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 06, 2014
Received: January 07, 2014

Dear Mr. Drizen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130781

Device Name
L.A.M. IPM Wound Gel/IPM Derm Gel

Indications for Use *(Describe)*
"OTC":

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• L.A.M. IPM Wound Gel/IPM Derm Gel is indicated for the management and relief of burning, itching and pain associated with various types of dermatoses; including atopic dermatitis, allergic contact dermatitis and radio-dermatitis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S